Newborn Screening
Quality Assurance Program

PROFICIENCY TESTING

Toxoplasma Quarterly Report

Volume 1, No. 4

November 2005

INTRODUCTION

The Anti-Toxoplasma Antibodies (IgM and IgG) pilot proficiency testing (PT) program is a new program initiated in 2005. This report is the quarterly summary of all data reported within the specified data-reporting period for Quarter 4, 2005. The attached tables provide the certification profiles for the distributed specimens, the verification of your reported data, the statistical analysis of the quantitative data, and the frequency distributions summary for expected interpretations. We distribute this PT report to all participants, state laboratory directors, and program colleagues by request.

On October 3, 2005, a panel of five unknown dried-blood-spot (DBS) specimens prepared from human serum positive for exposure to *Toxoplasma gondii* was distributed to 2 laboratories in the United States and 7 laboratories in other countries.

PARTICIPANTS' RESULTS

We processed data from 5 participants. Laboratories were asked to report IgM screening results in IU/mL blood or Absorbance (OD) units. For the statistical summary analysis, we did not include data that were outside the 99% confidence interval.

Three laboratories reported using AutoDelfia to measure anti-Toxoplasma IgM, 1 used Delfia, and 1 used "other" (Bio-Rad Quantase enzyme-linked immunoassay [EIA]).

The expected anti-Toxoplasma IgM values were based on CDC assayed values. Overall statistics from the AutoDelfia and Delfia methods were combined so as not to identify an individual laboratory. Results in OD units for the EIA method could not be combined with units for the Delfia methods and were not included in the summary statistics.

Expected interpretations (qualitative assessments) may differ by participant because of specific assessment practices. For participants that have provided us with their anti-Toxoplasma IgM cutoff value, we applied that cutoff in our final appraisal of the error judgment. Overall, participants reported no false-positive interpretations and 2 false-negative interpretations. The mean and mode cutoffs for AutoDelfia and Delfia participants were 6.5 and 4.0 IU/mL blood, respectively.

Participants were asked to confirm specimens that screened above their cutoff for sorting test results that were Toxoplasma antibody reactive from those that were Toxoplasma antibody non-reactive. Two laboratories reported using an immunosorbent agglutination assay (ISAGA) as a secondary screening or a confirmatory test.

The Newborn Screening Quality Assurance Program will ship next quarter's Anti-Toxoplamsa antibodies pilot PT specimens on January 9, 2006.

CDC/APHL

This program is cosponsored by the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL).

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CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-*TOXOPLASMA* IgM

QUARTER IV - NOVEMBER 2005

LAB XXX

SPECIMEN CERTIFICATION - IgM

CDC ASSAYED LEVELS

Analyte	Specimen 45T1	Specimen 45T2	Specimen 45T3	Specimen 45T4	Specimen 45T5
Anti-*Toxoplasma* Immunoglobulin M CDC Mean Assayed Value (IU/mL blood)	255 ± 14	88 ± 13	69 ± 8	9 ± 6	154 ± 9

EXPECTED INTERPRETATIONS

Interpretation	Specimen 45T1	Specimen 45T2	Specimen 45T3	Specimen 45T4	Specimen 45T5
Toxoplasma Antibodies	2	2	2	1	2

1 = *Toxoplasma* antibody non-reactive 2 = *Toxoplasma* antibody reactive NE = clinical assessment not evaluated

DATA VERIFICATION

Analyte	Specimen 45T1		Specimen 45T2		Specimen 45T3		Specimen 45T4		Specimen 45T5	
	Result	Code	Result	Code	Result	Code	Result	Code	Result	Code
Anti-*Toxoplasma* antibodies (IU/mL blood)										

Reviewer's Comments

EVALUATION:

1 = *Toxoplasma* antibody non-reactive 2 = *Toxoplasma* antibody reactive NE = clinical assessment not evaluated

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM

ANTI-TOXOPLASMA IgM

QUARTER IV - NOVEMBER 2005

OVERALL STATISTICS - IgM

Specimen	N*	Outliers	Mean	UL (95%)	LL (95%)
45T1	4	0	282	364	200
45T2	4	0	92	128	55
45T3	4	0	70	94	46
45T4	4	0	0	0	0
45T5	4	0	167	221	113

* Outliers are not included in N. UL = upper limit LL = lower limit

FREQUENCY DISTRIBUTION OF PARTICIPANTS' CLINICAL ASSESSMENTS

Specimen	Within Normal Limits	Outside Normal Limits
4581	0	5
4582	1	4
4583	1	4
4584	5	0
4585	0	5